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ATTORNEY'S DOCKET NUMBER: 2004367-0034

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Knaack *et al.* Examiner: Jagoe, Donna A.
Serial No: 10/771,736 Art Unit: 1614
Filing Date: February 4, 2004
Title: Polyurethanes for Osteoimplants

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

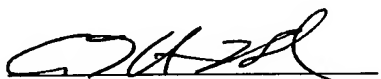
Sir:

TRANSMITTAL LETTER

Enclosed are the following documents:

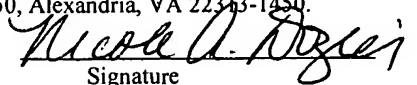
1. Statement under 37 C.F.R. §§ 1.56, 1.97, and 1.98 (6 pages);
2. Form PTO-1449 (4 pages);
3. Cited art (11 references); and
4. Return Postcard.

Respectfully submitted,


C. Hunter Baker, M.D., Ph.D.
Registration No. 46,533

Choate, Hall & Stewart, LLP
Two International Place
Boston, MA 02110
t (617) 248-5215
f (617) 248-4000
cbaker@choate.com

Dated: November 9, 2006

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Date	Signature
Nicole A. Dozier	
Typed or Printed Name of person signing certificate	



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Sir:

STATEMENT UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

Pursuant to the duty of disclosure under 37 C.F.R §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☒ [X] An *original* Information Disclosure Statement; or
☐ [] A *supplemental* Information Disclosure Statement.

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November 9, 2006

Date

Nicole A. Dozier
Signature

Nicole A. Dozier

Name of Person Signing

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
 - ☐ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
 - ☒ Before the mailing of a first Office action on the merits; or
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby certifies that *either*:
 - ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the

information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; or

☐ Includes herewith the fee set forth in § 1.17(p),

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; and

☐ Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☐ A copy of each cited reference not indicated with an asterisk is included, except for U.S. patents and published U.S. patent applications for which the submission requirements has been waived by the PTO in the Official Gazette Notice of August 5, 2003, for applications filed after June 30, 2003;
- ☒ A copy of each of the references cited on the attached form PTO-1449 (modified) is enclosed, except for U.S. patents and published U.S. patent applications for which the submission requirement has been waived by the PTO in the Official Gazette Notice of August 5, 2003, for applications filed after June 30, 2003;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☒ Does not contain non-English language citations;
- ☐ Includes one or more translations of a non-English citation; or
- ☐ Does contain non-English language citations

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC § 102.

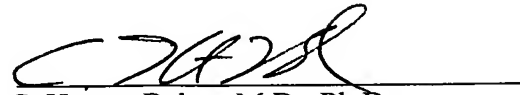
It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

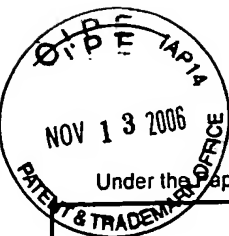
Respectfully submitted,

Dated: November 9, 2006

A handwritten signature in black ink, appearing to read 'CH Baker', is written over a horizontal line.

C. Hunter Baker, M.D., Ph.D.
Registration No. 46,533

Choate, Hall & Stewart, LLP
Two International Place
Boston, Massachusetts 02110
t (617) 248-5215
f (617) 248-4000
cbaker@choate.com



PTO/SB/08A (07-06)

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Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/771,736
Filing Date	February 4, 2004
First Named Inventor	Knaack, et al.
Art Unit	1614
Examiner Name	Jagoe, Donna A.
Attorney Docket Number	2004367-0034

Sheet 1 Of 2

U.S. PATENT DOCUMENTS

Examiner Initials	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US-RE 33,161	February 6, 1990	Brown, et al.	
		US-RE 33,221	May 22, 1990	Brown, et al.	
		US-4,880,610	November 14, 1989	Constantz	
		US-4,902,508	February 20, 1990	Badylak, et al.	
		US-5,034,059	July 23, 1991	Constantz	
		US-5,047,031	September 10, 1991	Constantz	
		US-5,053,212	October 1, 1991	Constantz	
		US-5,129,905	July 14, 1992	Constantz	
		US-5,149,368	September 22, 1992	Liu, et al.	
		US-5,243,038	September 7, 1993	Ferrari, et al.	
		US-5,262,166	November 16, 1993	Liu, et al.	
		US-5,263,984	November 23, 1993	Li, et al.	
		US-5,336,264	August 9, 1994	Constantz, et al.	
		US-5,462,722	October 31, 1995	Liu, et al.	
		US-5,507,810	April 16, 1996	Prewett, et al.	
		US-5,525,148	June 11, 1996	Chow, et al.	
		US-5,542,973	August 6, 1996	Chow, et al.	
		US-5,605,713	February 25, 1997	Boltong, et al.	
		US-5,607,269	March 4, 1997	Dowd, et al.	
		US-5,650,176	July 22, 1997	Lee, et al.	
		US-5,717,006	February 10, 1998	Daculsi, et al.	
		US-6,001,394	December 14, 1999	Daculsi, et al.	
		US-6,002,065	December 14, 1999	Constantz, et al.	
		US-6,206,957 B1	March 27, 2001	Driessens, et al.	
		US-6,294,187 B1	September 25, 2001	Boyce, et al.	
		US-6,696,073 B2	February 24, 2004	Boyce, et al.	
		US-2003/0039676 A1	February 27, 2003	Boyce, et al.	
		US-2003/0144743 A1	July 31, 2003	Edwards, et al.	
		US-2004/0024457 A1	February 5, 2004	Boyce, et al.	
		US-2004/0146543 A1	July 29, 2004	Shimp, et al.	
		US-2005/0008620 A1	January 13, 2005	Shimp, et al.	
		US-2005/0008672 A1	January 13, 2005	Winterbottom, et al.	
		US-2005/0013793	January 20, 2005	Beckman, et al.	
		US-2005/0031578 A1	February 10, 2005	Deslauriers, et al.	
		US-2005/0238683	October 27, 2005	Adhikari, et al.	

FOREIGN PATENT DOCUMENTS

Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns,	
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Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/771,736	
			Filing Date	February 4, 2004	
			First Named Inventor	Knaack, et al.	
			Art Unit	1614	
			Examiner Name	Jagoe, Donna A.	
Sheet	1	Of	2	Attorney Docket Number	2004367-0034

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Agrawal (eds.), et al., "Synthetic Bioabsorbable Polymers for Implants", Gorna and Gogolewski on Novel Polyurethanes, p. 39-57, July 2000.	
		Gunatillake, et al., "Biodegradable Synthetic Polymers for Tissue Engineering", <i>European Cells and Materials</i> , 5: 1-16, 2003.	
		Lewandrowski, et al., "Kinetics of cortical bone demineralization: Controlled demineralization-a new method for modifying cortical bone allografts", <i>J. Biomed. Materials Res.</i> , 31: 365-72, 1996.	
		Morlock, et al., "Duration and frequency of every day activities in total hip patients", <i>J. Biomech.</i> , 34: 873-81, 2001.	
		Reddi, et al., "Biochemical sequences in the transformation of normal fibroblasts in adolescent rats", <i>Proc. Nat. Acad. Sci. USA</i> , 69: 1601-5, 1972.	
		Urist, "A morphogenetic matrix for differentiation of bone tissue", <i>Calcif. Tissue Res.</i> , Suppl: 98-101, 1970.	
		Urist, "Bone: formation by autoinduction", <i>Science</i> , 150(698): 893-9, 1965.	
		Weiner, "Biologically-derived or biomimetic materials such as those identified in Lowenstam HA", <i>On Biomineralization</i> , Oxford University Press, 234, 1989.	
		Zhang, et al., "A new peptide-based urethane polymer: synthesis, biodegradation, and potential to support cell growth in vitro", <i>Biomaterials</i> , 21: 1247-58, 2000.	
		Zhang, et al., "Synthesis, Biodegradability, and Biocompatibility of Lysine Diisocyanate-Glucose Polymers", <i>Tis. Eng.</i> , 8(5): 771-85, 2002.	
		Zhang, et al., "Three-dimensional biocompatible ascorbic acid-containing scaffold for bone tissue engineering", <i>Tissue Engineering</i> , 9(6): 1143-57, 2003.	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 2313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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